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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,552	12/05/2003	Mark E. Deem	514362000204	4326

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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09/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,552

Applicant(s)

DEEM ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 07/13/2010.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2, 4-12, 31-32, 34-42 are rejected under 35 U.S.C. 102(b) as being anticipated by **Yoon** (U.S. Patent No. **5,542,949**).

Yoon discloses a tissue positioning device **40** having a first opening or port **86** in a first region or jaw **46** for releasably adhering a first area of tissue and an adjacent second opening or port **88** in a second region or jaw **48** for releasably adhering a

second area of tissue thereto (Figures 3-4 and 12-13; col. 3, lines 51-55, col. 7, lines 9-24), the first and second openings being separated by a longitudinally positioned septum **223/228** (Figures 16-17; col. 9, lines 25-29 – may be “positioned between parallel pairs of forceps jaws”); a plurality of fasteners or staples **54** housed within the device adapted to be deployed (Figure 2); and wherein the septum being removable from between the first and second openings to allow the at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue via the fastener (abstract; col. 9, lines 4-29). The tissue positioning device defines a slot (lumen of **42**) within which the septum is positionable. The first area and second area of tissue are adhered to the tissue positioning device via a vacuum created in the first region and the second region which are in fluid communication with a common channel **89** defined within the tissue positioning device that is separated via the septum (col. 7, lines 9-24). The septum is adapted to abrade adjacent tissue using a method consisting of cutting.

3. Claims 1-12, 31-42 are rejected under 35 U.S.C. 102(e) as being anticipated by **Adams et al.** (U.S. Patent No. **6,585,144**).

Adams et al. disclose a tissue positioning device or stapler device having a first opening or port **19** in a first region (distal region of slot between anvil member **10** and housing **12** in Figures 12-13) and an adjacent second opening or port **34** in a second region (proximal region of slot) both for releasably adhering a respective first area and second area of tissue during deployment of staples, the first and second openings being

separated by a septum ("staple retainer") **623** positionable within a slot (Figure 29), a plurality of fasteners or staples housed within the device, and wherein the septum is removable from between the first and second openings to allow the at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue. A plurality of additional regions for adhering additional tissue (other openings **19** and **34**) are defined in the tissue positioning device. The septum is longitudinally positioned in the tissue positioning device, wherein the longitudinal axis is formed from one end **631** of the septum to the other end **625** of the septum, and also defines a surface **627** that is adapted to abrade adjacent tissue, and may heat tissue as a result of abrading (Figures 27 and 29). The first and second areas of tissue may be adhered to the tissue positioning device via a vacuum created in the first and second regions (in the slot), since Adams et al. disclose utilizing suction through a common channel in fluid communication with the first and second regions an endoscope **8** (Figure 19c; col. 14, lines 56-64), wherein the common channel may be separated via the septum from the distal end of the device.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** (U.S. Patent No. **5,542,949**).

Yoon discloses the tissue positioning device as claimed except for the device defining a plurality of additional openings or ports for adhering additional tissue thereto.

It would have been obvious to one of ordinary skill in the art at the time of invention to provide additional ports or openings to the first and second regions of the tissue positioning device in order to increase the adhering capability of the device to further secure tissue and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Response to Arguments

6. Applicant's arguments filed 07/13/2010 have been fully considered but they are not persuasive.
7. Applicant argues that the port **86** is not part of the tissue positioning device **42**. The examiner clarifies above that the tissue positioning device is element **40**, not **42**.
8. Applicant generally argues that ports or openings **86** and **88** have the purpose of supplying/removing fluid, and are not disclosed as releasably adhering to the first and

second areas of tissues. However, ports **86** and **88** are capable of releasably adhering to a first and a second area of tissue and therefore read on the limitation, and the applicant does not argue that they are functionally incapable of suctioning tissue, but rather the ports are only disclosed as supplying or removing fluid rather than releasably adhering to tissue.

9. Applicant also argues that there is no explanation as to why the cutting member **223/228** is considered to be a "septum" and that that it is not placed in between the openings. The cutting member **223/228** is a "dividing partition between openings" since it may be "positioned between parallel pairs of forceps jaws" and therefore positioned between the openings **86** and **88** on the jaw (Figures 16-17; col. 9, lines 25-29). The cutting member may therefore be movable from between the first and second openings as recited in the claims.

10. In addition, applicant argues that the tissue is cut by the cutting member or septum after the fastener is put into place, and does not meet the limitation of the septum being removable from between the first and second openings to allow the at least one fastener to be put into place. Since the cutting member may move from between the openings and retract within the housing before applying the fastener, this meets the limitation. The method steps of removing the septum before deploying the fastener is not recited, but rather that the septum is capable of being removed in order "to allow" the fastener to be deployed.

11. Lastly in regards to Yoon, applicant argues that openings **86** and **88** are not in fluid communication with the inner hollow cylinder **89**. However, valve **62** can be

coupled with a vacuum source to create suction through the inner cylinder **89** via passages or tubes **86** and **88** (col. 7, lines 9-24) and therefore the openings must be in fluid communication with the inner hollow cylinder.

12. In regards to Adams, applicant argues that the ports **19**, **34** are not releasably adhered to tissue. However, when the staples are fired, before being released the ports and the stapler and anvil surfaces of the stapling device adheres to the first and second areas of tissue.

13. Next, applicant argues that the retainer or septum **623** remains in the slot (Figure 29) during deployment of the fastener, and therefore does not meet the limitation of being removable in order to allow the fastener to be deployed. The examiner disagrees. septum **623** is used to retain the staples during shipment, and once the device is removed from the package it is removed in order to calibrate an endoscope and also to allow deployment of the fastener (col. 21, line 50 to col. 22, line 11).

14. Lastly, applicant argues that Adams does not disclose the first and second area of tissue to be adhered to the tissue positioning device since the staple groove and staple slit surfaces do not have vacuum applied therein, or that the septum is longitudinally positioned or abrades tissue. However, as maintained above, the vacuum is applied in the first and second regions (in the slot), since Adams et al. disclose utilizing suction through a common channel in fluid communication with the first and second regions an endoscope **8** (Figure 19c; col. 14, lines 56-64), wherein the common channel may be separated via the septum from the distal end of the device. The septum is longitudinally positioned in the tissue positioning device, wherein a

longitudinal axis is formed from one end **631** of the septum to the other end **625** or the septum (not necessarily the longitudinal axis of the stapler), and also defines a surface **627** that is adapted to abrade adjacent tissue, and may heat tissue as a result of abrading (Figures 27 and 29).

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DIANE YABUT** whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734